Frequently Asked Quantum Grant Questions

Note: Words in italics are verbatim excerpts from the RFA

- 1. For the second phase of the Quantum Project (QG2), is the \$5M cap direct or total cost? (11/28/05)
 - **A.** The second phase can provide up to five million dollars per year in Total Costs.
- 2. Are there any necessary qualifications that the PI must have to apply for a Quantum Grant? (11/28/05)
 - **A.** Yes. Eligible principal investigators must have a track record in coordinating multi-investigator, interdisciplinary research programs.

The specific review criteria that will be used to assess the qualifications of the investigators are as follows: Are the investigators appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers? Does the investigative team bring complementary and integrated expertise to the project (if applicable)? Does the principal investigator have a record of successful leadership of an interdisciplinary team? Is there a demonstrated ability to recruit and coordinate co-investigators in areas outside the principal investigator's area of expertise? Are there appropriate teams identified to address the critical steps?

- 3. What qualifies as a Quantum Grant idea? (11/28/05)
 - A. The long-term goal of the Quantum Program is to make a profound (quantum level) advance in healthcare. It would develop technological methods to address a specific health care problem with a clear goal to produce a practical solution for the targeted problem. An example of the goal would be a demonstration of feasibility by providing substantial preclinical or "first-in-human" clinical data can be accomplished in a period of 10 years or less. Alternatively, Quantum projects may focus on technologies that broadly [and profoundly] impact and improve the practice of medicine. Examples of technologies that have produced a quantum advance and profoundly impacted human health include but are not limited to, the development of MR imaging, drug-eluting vascular stents, artificial hip and knee replacement, the cochlear implant, and renal dialysis. For specific scientific questions about quantum ideas, applicants are strongly advised to direct email to QuantumInfo@mail.nih.gov, or John Haller.

- 4. What if our technology has the potential to address a range of health problems, as opposed to the "targeted health problem" in your announcement? (11/28/05)
 - **A.** Quantum projects may focus on technologies that broadly [and profoundly] impact and improve the practice of medicine. For example, this might be a demonstration of feasibility by providing substantial preclinical or "first-in-human" clinical data that can be accomplished in a period of 10 years or less.
- 5. Does a quantum improvement in an existing technology qualify for a quantum grant? (11/28/05)
 - **A.** Yes, if the quantum improvement in the existing technology would result in a significant (quantum) advance in healthcare.
- 6. What are the requirements for a "multidisciplinary" or an "interdisciplinary" team? (11/28/05)
 - **A.** The team must be able to systematically solve all research questions associated with the Quantum Project. Sequentially or simultaneously, the team must ultimately address the individual components necessary to develop a prototype product that can be translated into a clinical product.
- 7. My work focuses on basic research. The knowledge that comes from this research will have a profound impact on our understanding of one or more diseases, and could potentially impact multiple diseases. Would this qualify as a Quantum Project? (11/28/05).
 - A. No. Applications that do not focus on the development and application of biomedical technologies will be considered non-responsive to this initiative. Applications that focus on underlying biomedical problems or mechanisms of disease, diagnosis, and prevention without a significant component to demonstrate a technological solution to a health care problem, will be considered non-responsive to this initiative.
- 8. Do you expect to have clinical trials in the Quantum Grants? (12/6/05)
 - A. No. The focus of the Quantum Grants is on technology development and not to support clinical trials. While clinical <u>studies</u> could be supported, and clinical trials are not excluded, clinical trials are likely far too expensive for the envisioned budgets available for the quantum projects. It might be possible to support very small phase I clinical trials, but the focus of the work must be on the technology development so that *feasibility by providing substantial preclinical or "first-in-human" clinical data can be accomplished in a period of 10 years or less.*

- 9. Do quantum grants require the development of new technology? (12/6/05)
 - **A.** The Quantum Grant should involve development of new technology or advancement of existing technology. In either case, the project must result in a significant (quantum) advance in healthcare.
- 10. Is prior approval needed for applications requesting \$500,000 or more in total-direct-cost per year? (12/6/05)
 - **A.** No. Nevertheless, independent of the budget requested, it is strongly suggested that all applicants discuss their potential project with an NIBIB program director and send in a Letter of Intent.
- 11. Will the discussions during the December 12 web/teleconference be confidential, or will our discussions with NIBIB regarding the specific research ideas of our proposal be made available to other research groups? (12/6/05)
 - A. The December 12 web/teleconference is a public forum. Discussions will be heard by all participants. Please do not divulge confidential information during this event. If you wish to discuss confidential matters, please communicate directly with an NIBIB program director.
- 12. What is the NIBIB's objective for this Quantum Grant program? (1/6/06)
 - **A.** The objective of this program is to have a profound impact on healthcare through technology development. The scientific research that is supported at the NIH today has the potential to impact the healthcare of tomorrow. The intent of the Quantum program is to focus some of these funds and translate promising research into profound improvements in healthcare.
- 13. Is it correct to say that the basic case that needs to be laid out in Phase I is a big healthcare problem, innovative technology development solution, focused effort to get there, and a plan on how to ramp up in the first three years? (1/6/06)
 - **A.** YES That's a perfect and succinct description!
- 14. Must a Quantum project target only one disease or can it be targeted to a couple of different diseases because our technology is commonly applicable? (1/6/06)
 - A. Even if your technology targets different or multiple diseases, it would be a good idea to tell the reviewers exactly how you might improve the condition, reduce suffering, or treat a particular disease, as an example, with the idea that your technology still may have broad applications for multiple diseases. You must also realize that you are competing against other applicants that have identified a particular disease as their problem and they're assembling their team and addressing the technological problems to solve that specific disease problem.

- 15. How is a Quantum Grant different from a center grant? Why is a P20 mechanism being used? What's the significance of the P20 mechanism? (1/6/06)
 - A. The P20 is an exploratory mechanism to assemble a team and demonstrate the feasibility of your idea. The P20 mechanism is much more flexible than the P01, P41 or similar mechanisms that many are familiar with, and the P20 was specifically chosen for its flexibility. There is no more explicit guidance on the P20, and there is no requirement for Developmental Projects, Cores, Career Development, Training, Service, or any of the other components typically involved in the P01 and P41. How you decide to structure and manage the multidisciplinary project is entirely up to you. The important thing to remember is that we are emphasizing clear deliverables and the P20 should contain a clear path to achieve them.
- 16. How much of the Phase II plans should appear in the Phase I proposal? Is it a line, a paragraph, or a page -- just to get an idea? (1/6/06)
 - A. In terms of what you hope to accomplish in Phase II, there should certainly be a sense of that (up to a few pages) in Phase I since that is preparing you for Phase II. This is not the same level of detail of the Phase I plan, but you should convince the reviewers that you have a reasonably robust plan to accomplish the project goals and solve a specific healthcare problem.